

200 C Street, SW
Washington, DC 20204

M-I-96-10 (Revision #4)

December 21, 2001

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Milk Safety Team (HFS-626)

SUBJECT: Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer Trace Back

This coded memorandum replaces and rescinds previous revisions of this memorandum (M-I-96-10).

This revision is based on action taken by the National Conference on Interstate Milk Shipments' (NCIMS) Executive Board following a Laboratory Committee Report given at an Executive Board meeting held at the 2001 NCIMS Conference, in Wichita, KS, and the phasing out of two (2) tests. It modifies the subject to reflect the provisions of M-a-86 (Revision #3) and modifies the tables to reflect the removal of the Lactek BL and Lactek CEF Beta lactam Milk Screening Kit as these tests have been phased out. For information regarding these tests please refer to M-I-96-10 (Revision #3) to see how these tests may be substituted for another equivalent test.

The following tables have been developed by FDA's Center for Veterinary Medicine (CVM) to demonstrate those screening tests that have been accepted under the requirements of Appendix N to determine whether presumptive positive tanker results are screening positive (load confirmation). These tables may also be used to determine an appropriate initial producer trace back test to identify the positive producer(s) who contributed the milk containing drug(s) on a positive load.

Note: Producers found presumptive positive by one (1) of these tests must be tested for confirmation using the same test that was used to determine the presumptive result for the producer. (See M-a-86 Revision #3)

These tables do not include any additional requirements for testing and are a reference for which tests are appropriate to test samples from a producer(s), which have contributed milk containing drug(s) to a positive bulk milk pickup tanker.

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. This memorandum will also be available on the FDA Web site at <http://www.cfsan.fda.gov> at a later date and should be widely distributed to representatives of the dairy industry, State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations and other interested parties.

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Milk Safety Team

**INITIAL POSITIVE
TEST**

CONFIRMATORY TEST OPTIONS

<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay</p>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Delvo-X-Press Beta lactam Test Kit Penzyme III Test Procedure Penzyme Milk Test SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Charm II Tablet Beta lactam Test (Competitive Assay)</p>	<p>Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvo-X-Press Beta lactam Residue Test Kit SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Charm II Tablet Beta lactam Test (Sequential Assay)</p>	<p>Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvo-X-Press Beta lactam Residue Test Kit SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Charm I/Cowside II Beta lactam Test</p>	<p>Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvo-X-Press Beta lactam Residue Test Kit</p>

**INITIAL POSITIVE
TEST**

CONFIRMATORY TEST OPTIONS

Charm I/Cowside II Beta lactam Test	SNAP Beta lactam Test Kit Parallux Beta lactam Assay
Charm II Tablet Beta lactam Test (Quantitative Assay)	Charm II Tablet Beta lactam Test (Quantitative Assay) Charm II Tablet Beta lactam Test (Competitive Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm I/Cowside II Tablet Beta lactam Test + Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay) Parallux Beta lactam Assay
Charm SL Beta lactam Test	Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvo-X-Press Beta lactam Residue Test Kit SNAP Beta lactam Test Kit Parallux Beta lactam Assay
Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay)	Charm II Tablet Beta lactam Test (Quantitative Assay) Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay) Charm II Test for Cloxacillin in Milk Parallux Beta lactam Assay
Charm II Test for Cloxacillin in Milk (Competitive Assay)	Charm II Tablet Beta lactam Test (Quantitative Assay) Charm II Test for Cloxacillin in Milk Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay) Parallux Beta lactam Assay
Charm II Tetracycline Drug Test	Charm II Tetracycline Drug Test
Charm II Sulfa Drug Test	Charm II Sulfa Drug Test

**INITIAL POSITIVE
TEST**

CONFIRMATORY TEST OPTIONS

<p>Delvotest P 5 Pack</p>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Delvo-X-Press Beta lactam Residue Test Kit Penzyme III Test Procedure Penzyme Milk Test SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Delvotest P/Delvotest P Mini</p>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta lactam Test Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Delvo-X-Press Beta lactam Residue Test Kit Penzyme III Test Procedure Penzyme Milk Test SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>

**INITIAL POSITIVE
TEST**

CONFIRMATORY TEST OPTIONS

<p>Delvotest SP/ Delvotest SP Mini</p>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Delvo-X-Press Beta lactam Residue Test Kit Penzyme III Test Procedure Penzyme Milk Test SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Delvo-X-Press Beta lactam Residue Test Kit</p>	<p>Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvo-X-Press Beta lactam Residue Test Kit SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>

**INITIAL POSITIVE
TEST**

CONFIRMATORY TEST OPTIONS

<p>Penzyme III Test Procedure</p>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Delvo-X-Press Beta lactam Residue Test Kit Penzyme III Test Procedure Penzyme Milk Test SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Penzyme Milk Test</p>	<p>Charm <i>B. stearothermophilus</i> Tablet Disk Assay Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvotest P 5 Pack Delvotest P/Delvotest P Mini Delvotest SP/Delvotest SP Mini Delvo-X-Press Beta lactam Residue Test Kit Penzyme III Test Procedure Penzyme Milk Test Parallax Beta lactam Assay</p>

**INITIAL POSITIVE
TEST**

CONFIRMATORY TEST OPTIONS

<p>SNAP Beta lactam Test Kit</p>	<p>Charm II Tablet Beta lactam Test (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) Charm I/Cowside II Tablet Beta lactam Test Charm II Tablet Beta lactam Test (Quantitative Assay) Charm SL Beta lactam Test Delvo-X-Press Beta lactam Residue Test Kit SNAP Beta lactam Test Kit Parallax Beta lactam Assay</p>
<p>Parallax Beta lactam Assay</p>	<p>Charm II Tablet Beta lactam Test (Quantitative Assay) Charm II Tablet Beta lactam Test (Competitive Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm II Tablet Beta lactam Test (Sequential Assay) + Charm II Test for Cloxacillin in Milk (Competitive Assay) Charm I/Cowside II Tablet Beta lactam Test + Charm I/Cowside II Test for Cloxacillin in Milk (Competitive Assay) Parallax Beta lactam Assay</p>